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From: Mike Shay <mshay@mum.edu> on 06/25/99 07:10 PM GMT

To: President@Whitehouse.GOV
cc:
Subject: FDAViolations Concerning G.E. Foods

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Dear President Clinton,

The FDA has once again violated U.S. law. In this case it can certainly be considered violations of human rights.

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Sincerely,

Michael Shay
2000 N. Court St 4D
Fairfield, IA 52556

The debate on genetically engineered foods comes to America...
A lawsuit recently uncovered documents showing disagreement within the
FDA
over the safety of gene-spliced foods.

For Immediate Release:
June 24, 1999

Lawsuit Uncovers Disagreement Within FDA Over Safety of Biotech Foods

Agency Contradicted Own Experts in Approving Genetically Engineered Foods --
Misrepresented Facts in Order to Promote U.S. Biotech Industry

Statement by Steven M. Druker, J.D., executive director of the Alliance
for
Bio-Integrity, coordinator of the lawsuit against the FDA to obtain mandatory
safety testing and labeling of gene-spliced foods, and an attorney on the
case (in collaboration with the legal department of the Center for Technology
Assessment in Washington, D.C.).

In May 1998, a coalition of public interest groups, scientists, and religious
leaders filed a landmark lawsuit against the U.S. Food and Drug Administration to obtain mandatory safety testing and labeling of all

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genetically engineered foods (Alliance for Bio-Integrity, et. al. v. Shalala). Nine eminent life scientists joined the coalition in order to

emphasize the degree to which they think FDA policy is scientifically unsound
and morally irresponsible. Now, the FDA's own files confirm how well-founded
are their concerns. The FDA was required to deliver copies of these files--totalling over 44,000 pages--to the plaintiffs' attorneys.

False Claims and a Policy at Odds with the Law

The FDA's records reveal it declared genetically engineered foods to be
safe
in the face of disagreement from its own experts--all the while claiming a
broad scientific consensus supported its stance. Internal reports and

memoranda disclose: (1) agency scientists repeatedly cautioned that foods
produced through recombinant DNA technology entail different risks than
do
their conventionally produced counterparts and (2) that this input was
consistently disregarded by the bureaucrats who crafted the agency's current
policy, which treats bioengineered foods the same as natural ones.

Besides contradicting the FDA's claim that its policy is science-based,
this
evidence shows the agency violated the U.S. Food, Drug and Cosmetic Act
in
allowing genetically engineered foods to be marketed without testing, on the
premise that they are generally recognized as safe by qualified experts.

FDA Scientists Protest Attempt to Equate Genetic Engineering with Conventional Breeding

The FDA admits it is operating under a directive "to foster" the U.S. biotech
industry; and this directive advocates the premise that bioengineered foods
are essentially the same as others. However, the agency's attempts to bend
its policy to conform with this premise met strong resistance from its
own

scientists, who repeatedly warned that genetic engineering differs from

conventional practices and entails a unique set of risks. Numerous agency
experts protested that drafts of the Statement of Policy were ignoring
the
recognized potential for bioengineering to produce unexpected toxins and
allergens in a different manner and to a different degree than do
conventional methods. According to Dr. Louis Priybl of the FDA Microbiology
Group, "There is a profound difference between the types of unexpected
effects from traditional breeding and genetic engineering which is just

glanced over in this document." He added that several aspects of gene

splicing "...may be more hazardous."

Dr. Linda Kahl, an FDA compliance officer, objected that the agency was

"...trying to fit a square peg into a round hole ... [by] trying to force an
ultimate conclusion that there is no difference between foods modified
by
genetic engineering and foods modified by traditional breeding practices."
She said: "The processes of genetic engineering and traditional breeding are
different, and according to the technical experts in the agency, they lead to
different risks." Moreover, Dr. Jim Maryanski, the FDA Biotechnology
Coordinator, acknowledged there is no consensus about the safety of
genetically engineered foods in the scientific community at large, and
FDA
scientists advised they should undergo special testing, including
toxicological tests.

Misrepresenting the Facts in Order to Approve the Foods

Nonetheless, so strong was the FDA's motivation to promote the biotech
industry that it not only disregarded the warnings of its own scientists
about the unique risks of gene-spliced foods, it dismissed them and took a
public position that was the opposite. Its official policy asserts: "The

agency is not aware of any information showing that foods derived by these
new methods differ from other foods in any meaningful or uniform way...."
Thus, although agency experts advised that genetically engineered foods

should be subjected to special testing, the bureaucrats in charge of the
policy proclaimed these foods require no testing at all.

Violating Federal Law

Besides violating basic canons of ethics, the FDA's behavior flagrantly

violates the U.S. Food, Drug and Cosmetic Act, which mandates that new
food
additives be established as safe through testing prior to marketing. While
the FDA admits that bioengineered organisms fall under this provision,
it
claims they are exempt from testing because they are "generally recognized as
safe" (GRAS), even though it knows they are not recognized as safe even
by
its own scientists let alone by a consensus in the scientific community.
Further, the statute prescribes that additives like those in bioengineered
foods can only be recognized as safe on the basis of tests that have
established their harmlessness. But no such tests exist for gene-spliced
foods. So, although the GRAS exemption was intended to permit marketing
of
substances whose safety has already been demonstrated through testing,
the
FDA is using it to circumvent testing and to approve substances based largely
on conjecture--conjecture that is dubious in the eyes of its own and many
other experts.

Consequently, every genetically engineered food in the U.S. is on the market
illegally and should be recalled for rigorous safety testing. The FDA has
deliberately unleashed a host of potentially harmful foods onto American

dinner tables in blatant violation of U.S. law.

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